REMARKS

Claims 1-9, 11-14, and 26-44 are pending in the application. In this response, no claim amendments are made. Claims 1-9, 11-14, and 26-44 remain pending for consideration.

Reconsideration and allowance of the claims as pending are respectfully requested. This response after final rejection should be entered, as the response will place the application in condition for allowance or in better form for appeal.

Claim Rejection - 35 USC § 102

Claims 1, 2, 9, 11-12, 14, 26-29, 35, 39, and 43 are rejected under 35 U.S.C. §102(b) as being anticipated by Sharkey et al. (U.S. Patent 5,540,701). The rejection is traversed.

The Sharkey et al. reference is directed to a "passive fixation anastomosis device" and a catheter to install the device. As shown in Figures 11-13 of Sharkey et al., the catheter 18 includes two balloons 32, 36 that can be inflated to install fixation device 10 for anastomosis of a body lumen. In particular, the balloons cause a proximal end 12 and a distal end 14 of fixation device 10 (separate from the catheter) to be expanded to deployed positions, and the catheter is subsequently removed to leave the passive fixation anastomosis device (10) in place.

Pending independent claims 1, 9 and 26 provide that the tissue approximating structure (claim 1), tissue approximating means (claim 9) and second tissue approximating structure (claim 26) are "elongate." The Office Action indicates that balloons 32, 36 of Sharkey et al. are elongate tissue approximating structures. This analysis misconstrues the meaning of the term "elongate," especially as that term is used in the pending application.

The Office action cites mention in the Sharkey reference that a balloon may be "generally cylindrical," and bases upon this very general notion the conclusion that a generally cylindrical balloon "may be considered" to be "elongate." There are at least two problems with a rejection on these stated grounds. A first is that the rejection is conclusory. The rejection contains no analysis or explanation as to what aspect of a cylindrical balloon would be considered "elongate," but merely states summarily that a cylindrical balloon "may be considered elongate."

The lack of explanation leaves open important questions such as the idea of which particular feature of a cylindrical balloon is "elongate." A cylinder includes a hollow interior and a substantially two-dimensional "circular" body. The Office action does not explain whether the cylinder is thought to embody an "elongate" axis, or is "elongate" at part of the two-dimensional body. If a cylindrical axis is considered "elongate," one cannot necessarily conclude that the cylindrical balloon, i.e., the "body" that makes up a balloon surface (which would form a tissue approximating structure) is "elongate." For instance, not all two-dimensional balloon surfaces can be said to be "elongate." If the rejection concludes that the two-dimensional cylindrical surface of a cylindrical balloon is considered "elongate," Applicants would not agree that a two-dimensional expandable balloon surface "may be considered elongate." A rejection with more explanation as to the "elongate" feature of the balloon would point out with some degree of explanation, the particular feature of the balloon (e.g., longitudinal axis, or expandable two-dimensional surface) that is considered to be potentially "elongate," to allow Applicants to address the rejection with a fair response based on the understood reasoning of the rejection.

A second problem with this basis of rejection is that the rejection, premised on an asserted lack of novelty under 35 U.S.C. section 102, would require that a cylindrical balloon is inherently elongate. To be a legally inherent feature of a balloon, all "generally cylindrical" balloons would have to be "elongate" -- the rule of inherency requires that a feature, to be inherent, must necessarily be present in the prior art reference, and that to be necessarily present, the feature must be more than a mere probability or possibility. Even without the benefit of an explanation of how a "generally cylindrical" balloon is elongate, it is possible to envision a balloon that is not "elongate." A definition of "elongate is "having more length than width; slender." See www.thefreedictionary.com/elongate. A cylindrical balloon does not necessarily have more length than width, and therefore cannot be conclusively and inherently assumed to be elongate.

Separate from the above review of the rejection, pending independent claims 1, 9, and 26, when properly read in view of the pending patent specification, are clear to not read on a balloon. The pending application specifically distinguishes balloon structures

from elongate tissue approximating structures. Although the Patent Office may give claims and claim elements a broad reasonable construction, any such construction must be "consistent with the specification, . . . [C]laim language should be read in light of the specification." In re Bond, 910 F.2d 881, 883 (Fed. Cir. 1990). Throughout the specification of the pending application, Applicants have distinguished balloon tissue approximating structures from elongate tissue approximating structures. In paragraph [0030], Applicants indicate that "the tissue approximating structure may include, for example, one or multiple balloons or balloon-like structures" and that "alternately, the tissue approximating structure may include elongate structures such as a needle, tine, prod, probe, or the like." (Emphasis added.) Based on at least these passages taken directly from the specification of the pending patent application, a balloon or balloon-like tissue approximating structure is not to be considered an "elongate tissue approximating structure." Accordingly, the rejection, which is based on the interpretation that a cylindrical balloon is necessarily (i.e., inherently) "elongate," cannot be sustained.

Paragraph [0030] of the pending application continues that "combinations of balloons and elongate structures may also be useful in certain applications," again distinguishing balloons from elongate structures.

Paragraphs [0035] and [0036] of the application continues distinguishing the two different structures. Paragraph [0035] discusses exemplary elongate tissue approximating structures and provides examples of movable elongate tine or needle type structures. Paragraph [0036] states that "alternately, the tissue approximating structure may include one or two balloons" (emphasis added herein).

Paragraphs [0030] and [0035], [0036] make clear that there is a distinction between elongate tissue approximating structures and tissue approximating balloons. Because the terms of the claims must be read in light of the specification, based on the definition provided in the specification of the pending application, the balloons 32, 36 of Sharkey et al. cannot be elongate tissue approximating structures.

At least for these reasons, because a balloon of Sharkey et al. is not an elongate tissue approximating structure, Sharkey et al. does not anticipate claims 1, 2, 9, 11-12, 14, 26-29, 35, 39 and 43. Accordingly, it is respectfully requested that the rejection of claims 1, 2, 9, 11-12, 14, 26-29, 35, 39 and 43 under 35 U.S.C. §102(b) be withdrawn.

Claim Rejection - 35 USC § 103

Claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharkey et al. (U.S. Patent 5,540,701) in view of Kirsch et al. (U.S. Patent 6,461,367). The rejection is traversed.

The pending claims require "elongate" tissue approximating structure, with various claims more precisely defining the elongate tissue approximating structure. Independent claim 1 discussed above requires: elongate tissue approximating structure that can be extended and retracted from the catheter body wall. Independent claim 9 requires elongate tissue approximating means, wherein the tissue approximating means can be extended and retracted from the catheter body wall. Independent claim 26 requires first and second tissue approximating structure that can be extended and retracted from the catheter body wall, and that the second tissue approximating structure comprises elongate structure. Independent claim 32 requires a tissue approximating structure comprising movable elongate structure selected from a tine, a probe, a prod, and a needle.

Claims 3-8 and 36-38 depend either directly or indirectly from independent claim 1. Claim 3 recites that the elongate tissue approximating structure is a tine, a probe, a prod, or a needle, and claim 4 recites that they can be extended and retracted. Claim 5 recites movable elongate tissue approximating structure and claim 6 recites movable elongate tines. Claims 7 and 35 recite multiple tines and claim 8 recites multiple opposing tines. Claim 37 recites two sets of multiple tines.

Claims 13 and 40-42 depend, either directly or indirectly, from independent claim 9. Claim 13 recites movable tine. Claim 40 recites multiple tines. Claim 41 recites two sets of multiple tines. Claim 42 requires fixed relative positioning of the balloon.

Claims 30-31 and 44 depend indirectly from independent claim 26. Claim 30 recites movable tine, a probe, a prod, or a needle. Claim 31 recites multiple opposing tines. Claim 44 recites multiple tines.

Claims 33-34 depend from independent claim 32, which recites that the tissue approximating device is a movable elongate tine, a probe, a prod, or a needle. Claim 34 recites two sets of movable multiple tines.

The Office Action states that Sharkey et al. disclose the claimed device "except for the tissue approximating structure or the second tissue approximating structure comprising of multiple distal tines and multiple proximal tines." (See the Office Action at page 4.) This is incorrect. As discussed above, the Sharkey reference does not disclose elongate tissue approximating structures; as presented and convincingly supported above, a balloon is not an "elongate tissue approximating structure" as claimed.

Moreover, one of skill would not have had any motivation to replace the balloon of the Sharkey device with an "elongate" replacement structure, such as the Kirsch structure. To the contrary, replacing the expanding (non-elongate) two-dimensional balloon surface with an "elongate" structure (e.g., having more length than width; slender) as shown by Kirsch et al., would cause the Sharkey device to be inoperable or at least be less advantageous than the use of the Sharkey balloon.

The balloon of Sharkey et al. provides an expanding two-dimensional surface area designed create an expanding portion of the catheter, that, upon expanding, presses laterally (in a direction perpendicular to the length of the shaft) against an end of a passive fixation device. The structure of the balloon includes an expanding surface area that can contact the end structure of a passive fixation device, and place lateral pressure on the end of the fixation device, the lateral pressure being exerted in a direction away from (perpendicular to) the shaft. The reference provides a brief, vague comment that a "distensible member" can be used in place of the balloons 32, 36. The "distensible member" is said to be "mechanically extended and retracted in order to deploy proximal and distal ends 12 and 14. But, the reference does not indicate that a "distensible member" may be "elongate" or of any other particular form. To the contrary, one of skill might consider that a "distensible member" be in the form of a mechanical replacement of an expandable (inflatable) balloon, i.e., an expandable mechanical two-dimensional surface. There is no suggestion that an "extensible member" is "elongate," or is a "tine, a probe, a prod, or a needle." Because the Sharkey reference does not indicate the nature of the structure of a "distensible member," only speculation or improper hindsight would lead to the conclusion that one of skill would replace a <u>two-dimensional expanding</u>

balloon surface with a "distensible member" having the form of an "elongate" "tine," "probe," "prod," or "needle," or "multiple opposing tines."

Regarding the Kirsch structures, these are designed to manipulate opposing luminal tissue to approximate two opposing severed lumens for anastomosis. For that reason, the structures extend from a shaft at an acute angle relative to the shaft, not laterally (perpendicular) from the shaft. The lateral extension allows the structures to place longitudinal force on the tissue to allow approximation of the opposing severed luminal tissues. Of course the Sharkey balloon is not designed to manipulate opposing luminal tissue for approximation, so the design and function are completely different. One of skill would readily identify that the Kirsch structures are not designed and are not necessarily suitable to perform the function of the balloon of Sharkey. The Sharkey balloon is especially designed to laterally expand an expandable end of a passive fixation device by placing lateral (perpendicular) pressure on the expandable end -- any net non-lateral pressure would not be desired, and would be avoided.

Consider that the Sharkey balloon expands laterally, without substantial net longitudinal force. The Kirsch structure expands partially laterally, but also with a substantial longitudinal component that would exert pressure in a longitudinal direction, along the length of the shaft, so the structures can hold opposing luminal tissue together for anastomosis. The longitudinal pressure, while an intended and necessary feature of the Kirsch structure, would be undesirable if placed on the end of the Sharkey passive fixation device, because the end of the Sharkey device would receive longitudinal pressure relative to the shaft of the insertion device, which would frustrate accurate placement of the passive fixation device. Longitudinal pressure would not be useful, but would be undesired, because, for example, longitudinal pressure would tend to move the passive fixation device longitudinally, which would be a disadvantage when placing the passive fixation device within a patient. At least for this reason, one of skill would not only have failed to use the Kirsch structure as a replacement for the Sharkey balloon, but would have in fact avoided the use of the Kirsch structure as a replacement for the Sharkey balloon.

Further distinguishing certain pending claims is the feature of opposing (e.g., proximal and distal) elongate tissue approximating structures (e.g., tines); see claims 8, 31, 37, 38, 41 and

42. The Office Action, citing figures 11A-13 of Kirsch et al., concludes that the figures show opposing tines on a catheter body wall.

Applicants disagree. Figures 11A-13 do not show opposing tines on a device as recited by the pending claims. Figure 4 of the pending application illustrates an example of opposed elongate tissue approximating structures (e.g., tines 54, 56) positioned along catheter body 42. Figures 11A and 11B of the Kirsch reference illustrate a pair of everting prongs 30 present on trocar 16, and a pair of everting prongs 30 present on a different device, sheath 24. Everting prongs 30 on trocar 16 are not on the same catheter body as everting prongs 16 on sheath 24. The two pairs of everting prongs are not on the same structure, and thus are not opposing elongate tissue approximating structures or tines on a catheter body, as required by the pending claims.

At least because the Examiner has not provided a *prima facie* case of obviousness to use the prongs of Kirsch et al. in lieu of expanding balloons in the device of Sharkey et al., claims 3-8, 13, 30-34, 36-38, 40-42, and 44 are patentable. Accordingly, it is respectfully requested that the rejection of claims 3-8, 13, 30-34, 36-38, 40-42, and 44 under 35 U.S.C. §103(a) be withdrawn.

Conclusion

In view of the present remarks, Applicants submit that the outstanding rejections have been either overcome or should otherwise be withdrawn. Reconsideration of the claims, and allowance of the pending claims, are respectfully requested.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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By: _____

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